2-STEP ROCKSTAR POLISH System

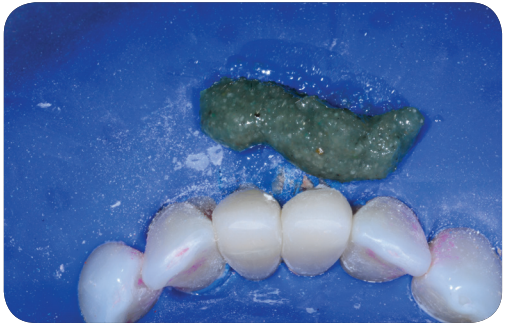
INSTRUCTIONS FOR USE

BIOCLEAR

ROCKSTAR SYSTEM

Each component of the system is designed to have 2 phases

- **Magic Mix** – contains both large and small particles
- **RS Polisher** – first use dry then use wet



PRE-MEASURE MAGIC MIX PASTE

Put a fair amount of Magic Mix Pre-Polisher Paste into a dappen dish from the container to avoid contamination. For each tooth, place a fair amount of paste on a neighboring tooth or on the rubber dam near the tooth for easier access during polishing.

***Tip**: Gather around 2 full scoops of Magic Mix Paste using The Magic Mix Cup (around the size of a pea total) for 1 whole tooth*

BEGIN PRE-POLISH

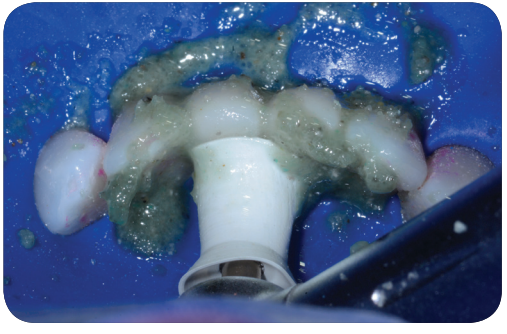
Scoop a small amount into The Magic Mix Cup to begin polishing.

***Tip**: Do not completely fill the Magic Mix Cup with polisher when you begin polishing because if there is too much in the cup it will spin off the tooth immediately. Use smaller amounts and refresh often. Use pulsing pressure and move around the tooth because Magic Mix can generate heat (don't put constant pressure in one spot on the tooth for more than 3 seconds at a time.)*

REFRESH PASTE OFTEN

Particles in the paste spin away from the tooth during the pre-polish. Refresh with fresh magic mix in the cup every 2-3 seconds.

***Tip**: Don't forget to flange in between the teeth with cup and Magic Mix Paste*

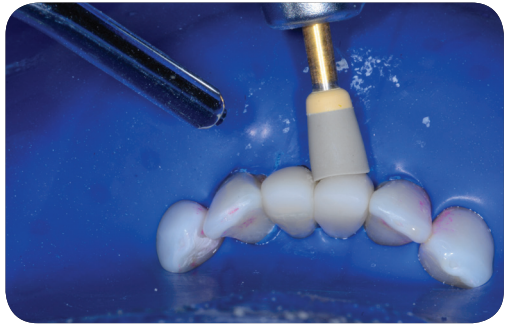


REDUCE PRESSURE

Once rough polishing is done and only the smaller particles remain, proceed to the second phase of this stage: Run the cup and remaining paste lightly over the tooth with the big chunks gone.

RINSE

Rinse off any remaining Magic Mix Paste.



USE RS POLISHER DRY

Start by using the RS Polisher dry with medium pressure. Make sure to blow air on it to keep the restoration from getting too hot, but some heat is good. This step should comprise 2/3 of the time spent on the final polish.

***Tip**: Using the RS Polisher dry creates light heat friction which creates more rapid finishing. The entirety of the final polishing with the RS Polisher can be done with water, however it will take longer because heat friction won't be utilized.*

USE RS POLISHER WET

For the remainder of the final polish, use the RS Polisher with water.

AFTER FINAL POLISH

"Patients absolutly love the feel of the Bioclear Method with the Rockstar Polish. The Rockstar Polish is one of the four cornerstornes of the Bioclear Method. It will set your restorations apart from traditional 'bonding'."

-Dr. David Clark

CLEANING & STERILIZATION INSTRUCTIONS

Magic Mix Pre-polish Paste and Magic Mix Pre-Polish Cups are single-use only. RS Polisher Cups are reusable and autoclavable. See below for instructions.

PRE-TREATMENT

Equipment: plastic brush (e.g. Interlock, #09084), tap water (20± 2 °C) (at least drinking water quality)

1. Pre-clean under running water with a brush (plastic) directly after use.
2. Rinse the polishers under running water for 60 seconds and brush them thoroughly with a plastic brush, particularly the difficult to access areas of the head (bristles, silicone bristle tips).

CLEANING: MANUAL

Equipment: Multi-stage enzymatic cleaner (e.g. Dürr Dental, ID 215), tap water/flowing water (20± 2 °C) (at least drinking water quality), ultrasonic bath (e.g. Sonorex Digital 10P)

Note: Coarse surface contamination on the instruments must be removed before manual reprocessing (see pre-treatment)

1. Prepare the cleaning solution according to the manufacturer's instructions (Dürr Dental ID 215 2% solution was validated) and fill into an ultrasonic bath.
2. Completely immerse the polishers in the solution.
3. Expose the products for 1 minute to the ultrasonic bath.
4. Remove the polishers from the cleaning solution and rinse them each thoroughly (30 seconds) under running water.
5. Check for cleanliness. If contamination is still visible, repeat the above specified steps.

DISINFECTION: MANUAL

Equipment: At least limited virucidal instrument disinfectant (VAH listed - or at least listed in the IHO with testing according to DW) e.g. based on quaternary ammonium compound(s), alky¬lamine(s)/alkylamine derivative(s), guanidine(s)/guanidine derivative(s) (e.g. Dürr Dental, ID 212), preferably fully deionized water (deionized water, according to

KRINKO/BfArM recommendation free of facultatively pathogenic micro-organisms), ultrasonic bath (e.g. Sonorex Digital 10P), lint-free sterile cloth.

1. Prepare the disinfectant solution according to the manufacturer's instructions (Dürr Dental ID 212, 2% solution was validated) and place into an ultrasonic bath.
2. Completely immerse the polishers in the disinfectant solution.
3. Expose the products for 2 minutes to the ultrasonic bath.
4. Further exposure time to the disinfectant solution for 5 minutes according to the disinfectant manufacturer's instructions.
5. Remove the polishers from the disinfectant solution and allow to drip off.
6. Rinse the products with deionized water for 30 seconds.
7. Wipe with a single use sterile lint-free cloth or, if necessary, dry with medical compressed air.

CLEANING AND DISINFECTION: AUTOMATIC

Equipment: Cleaning and disinfection unit according to DIN EN ISO 15883-1+2 with thermal program (temperature 90 °C to 95 °C), detergent: mildly alkaline detergent (e.g. Dr. Weigert -neodisher MediClean Dental).

Note: Coarse surface contamination on the instruments must be removed prior to automatic reprocessing (see pre-treatment)

1. Place the instruments in a suitable small parts tray or on the load carrier such that all surfaces of the instruments are cleaned and disinfected.
2. Close WD and start program, see table below for program sequence.

PROG. STEP	WATER	DOSAGE	TIME	TEMP
Pre-rinse	CW		5 Min	
Dosage of detergent		According to manufacturer's instructions		According to manufacturer's instructions
Clean	Fully deionized water		10 Min	55° C
Rinse	Fully deionized water		2 Min	
Disinfect	Fully deionized water		3 Min	Ao-value > 30001 (e.g. 90° C, 5 min)
Drying			15 Min	Up to 120° C

[1] Authorities may issue other operational regulations (disinfection performance parameters) in their area of competence.

3. Remove the instruments at the end of the program.
4. Check that the load is dry and, if necessary, dry with medical compressed air.
5. Visual inspection for cleanliness is performed after removal from the WD. If contamination is still visible, reclean medical devices again manually. Subsequently, the recleaned medical devices must again be reprocessed automatically.

PACKAGING

Equipment: Film-paper packaging (e.g. steriCLIN, art. no. 3FKFB210112 and 3FKFB210140), sealing device (e.g. HAWO, type 880 DC-V) . A suitable method (sterile barrier system) is to be used to package the instruments. Packaging according to DIN EN ISO 11607. A sterile barrier system (e.g. film-paper packaging) according to DIN EN ISO 11607 is to be used, which is intended for steam sterilization by the manufacturer. The instruments are double packed. The packaging must be large enough to avoid stressing the sealing seam.

Note: After the heat sealing process, the sealing seam must be checked visually for any defects. In case of defects, the packaging must be opened and the instrument repacked and sealed.

STERILISATION

Device: Sterilizer according to DIN EN 285 or small steam sterilizer according to DIN EN 13060, type B process

Process: Steam sterilization with fractionated pre-vacuum, 134 °C, holding time min. 3 min (in Germany according to KRINKO/BfArM recommendation 134 °C min. 5 min) or 132 °C min. 3 min (parameter of validation). Longer holding times are possible.

1. Place the packaged products in the sterilization chamber.
2. Start the program.
3. Remove the products at the end of the program and allow to cool down.
4. Then check the packaging for possible damage and screening effects. Faulted packaging must be regarded as being non-sterile. The instruments must be repacked and sterilized.

STORAGE

Store away from direct sunlight or extreme heat.

RS POLISHER OTHER NOTES

- Observe the manufacturer's information on material compatibilities for cleaning, disinfection and sterilization.
- All instruments are delivered unsterile and must go through the indicated cycle before and after each use.
- Strong acids and strong bases may oxidize the stainless steel shank.
- Avoid temperatures >150 °C.
- Ultrasonic bath must not exceed temperatures of 42 °C because of the possible coagulation of protein.
- Instruments that have not completely dried after cleaning and disinfection must be dried again (e.g. with medical compressed air) to avoid compromising the success of sterilization.
- Instructions of cleaning and/or disinfecting solutions must specifically state "suitable for rubber polishers or synthetics/ silicones". The exposure time and concentration specified by the manufacturer must be followed.
- Repetitive reprocessing can slightly change both the look and feel of the product, but does not interfere with the instrument's function.

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